



Cochise Regional Hospital Hematology and Urinalysis Policies and Procedures

Quality Control

POLICY

It is the policy of Southeast Arizona Medical Center Laboratory to follow all current federal, state and manufacturer's requirements for quality control for all lab testing.

PROCEDURE

Below is a quality control program for each clinical lab area. Quality Control data in each area is printed and reviewed at least monthly by the supervisor.

Chemistry (Architect i1000)

1. Two levels of chemistry control are run each day of use. Standards or calibrations are run as outlined by each procedure. Assays are calibrated as needed by the manufacturer's recommendations, each new lot number change, or as needed per the QC Troubleshooting procedure.
2. Participation in a JCAHO/CLIA/CAP approved proficiency program.

Immunochemistry (Architect i1000)

1. Two levels of chemistry control are run each day of use.
2. Calibrations are run as outlined by each procedure. Assays are calibrated as needed by the manufacturer's recommendations, each new lot number change, or as needed per the QC Troubleshooting procedure.
3. Participation in a JCAHO/CLIA/CAP approved proficiency program.

Hematology (Ruby Cell Dyn)

1. Two levels of Ruby Cell Dyn are run each 8 hour shift in use.
2. If a manual differential is performed it is evaluated by the technologist for agreement with the Ruby results.
3. Participation in a JCAHO/CLIA/CAP approved proficiency program.

Coagulation

1. Two levels of Dade ci-Trol Coagulation controls are run each 8 hour shift in use.
2. Participation in a JCAHO/CLIA/CAP approved proficiency program.

Sedimentation Rates

1. Two levels of Polymedco Sed Chek Controls are run each day in use.
2. Participation in Polymedco Quality Assurance Program.
3. Participation in a JCAHO/CLIA/CAP approved proficiency program.



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Urinalysis

1. Two levels of Kova-Trol are run each day of use.
2. Participation in a JCAHO/CLIA/CAP approved proficiency program.

Serology

1. Each kit has manufacturer supplied controls that are run as per manufacturer's recommendations.
2. Participation in a JCAHO/CLIAJCAP approved proficiency program.

Blood Bank

1. Ortho Confidence system is performed each day of use.
2. Participation in a JCAHO/CLIAJCAP approved proficiency program.

Microbiology

1. Gram Stains are done on slides with known organisms.
2. Rapid Strep Kits are Qc'd with each lot number change or on the first of each month. Internal control results are documented on each test performed.
3. Participation in a JCAHO/CLIA/CAP approved proficiency program.



Quality Control Troubleshooting Protocol for QC Out of Control

Quality Control programs exist in all laboratory areas. When Quality Control values fall outside the established limits, the following steps shall be followed:

1. Do not report patient results.
2. Review procedures and analytic system for identifiable errors.
3. Pour or reconstitute fresh control(s). Run both prior control(s) and fresh control(s).
 - a. If fresh control(s) is/are within limits, repeat the patient run and report. Include a fresh control with the repeat patient run.
 - b. If fresh control(s) and repeat control(s) remain unacceptable, make or change reagent.
4. Rerun control(s) using new reagent.
 - a. If control(s) is/are now within limits, repeat patient run (including a control) and report results.
 - b. If control(s) remain unacceptable, troubleshoot procedure or instrument in conjunction with the primary operator, hotline personnel or lab manager.
5. Discard any control material/reagents which yield unacceptable results.
6. Do not report any patient results until you have an acceptable control run.
7. Document all action taken in the work/troubleshooting log. Plot all control values including those out of range.



CALIBRATIONS

Principle

Calibrations provide a standard of analysis using preset determinations in order to establish continuity of quality control.

Policy

It is the policy of Southeast Arizona Medical Center Laboratory to perform calibrations on the following instruments:

Ruby Cell Dyn

1. Calibrations are to be run: every 6 months.
2. Calibrations are to be run: when any instrumentation has been replaced.
3. Calibrations are to be run: when drifts and trends in quality control/correlations appear.

CA-500

1. Calibrations are to be run: every 6 months.
2. Calibrations are to be run: with each new lot number of control for DDIMER
3. Calibrations are to be run: with-each new lot-number of PT Recombinant Reagent:
4. Calibrations are to be run: when drifts and trends in quality control/correlations appear.

Architect C400

1. Calibrations are to be run: according to manufacturer's instructions.
2. Calibrations are to be run: for Basic Metabolic profile every 8 hours.
3. Calibrations are to be run: for each new lot number of reagent.
4. Calibrations are to be run: for Drugs of Abuse once a week
5. Calibrations are to be run: when drifts or trends appear in quality control/correlations.

Architect i1000

1. Calibrations are to be run: According to manufacturer's instructions.
2. Calibrations are to be run: for each new lot number of reagent.
3. Calibrations are to be run: when drifts or trends appear in quality control.



Calibration Verification

Principle

Calibration verifications are performed in order to validate calibrations and quality control.

Policy

It is the policy of Cochise Regional Hospital Laboratory to run calibration verification testing every six months.

Materials

Chemistry - Maine Standards Validate Kits.

Glucometers - RNA Medical Glucose Calibration Verification Control

Hematology/Streak CVA for cell-Dyn

Procedure

1. Run linearity kits for each analyte according to manufacturer's instructions.
2. Fill out appropriate paperwork per kit.
3. Include instrument printouts and give results to Lab Manager.
4. Notify Lab Manager of any problems.



Operation of the Cell-dyn Ruby Hematology Analyzer

PRINCIPLE

The cell-dyn Ruby is a multi-parameter automated hematology analyzer for in vitro diagnostic use in counting and characterizing blood cells, with the capability of a five part leukocyte differential by flow cytometry which uses a laser beam to intersect cells, light is scatter at different angles that are measure to give the data about cells. Ruby is capable of running in both modes open and closed; with the purpose of identify patient results with normal system generating parameters and to flag patient's data that require additional studies. Ruby also has an automated reticulocyte mode.

START UP

At the beginning of the day the system shall be on standby, but if the system is idle for 4 hours it automatically goes into standby, then F12-prime key must be pressed to run a background count which is used to confirm that the system's baseline performance meets stated criteria; if results are within acceptable ranges proceed to run QC.

DAILY QUALITY CONTROL

- 1-Two controls shall be run every 8 hours.
- 2-Controls shall be run following a background count (Prime).

OPERATION- CBC

- 1-From the main screen press F11 to select the mode desirable to be run.
- 2-If closed mode is to be run load the specimen with the barcode on the rack and place it on the loader and press F12. Ruby has a cap piercing system that will allow running closed tubes.
- 3-If open mode is to be run, input the patient's information in the next open tube entry either manually or using the hand-held bar code reader.
- 4-Mix the specimen according to the manufacturer's recommendation.
- 5-Place the specimen under the aspiration probe, raise the tube until the end of the probe is deeply immersed in the sample.
- 6-Press the touch plate behind the probe to start the run cycle, and take out the specimen while the rinsing probe pushes the specimen down.
- 7-Results are displayed on the run view screen and printed automatically if auto print is on.



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QUALITY CONTROL OUT OF CONTROL

Department: _____ Month/Year _____ Rey.By/Date: _____

Reviewed: 11/14

Reviewed: 11/14



Correlation of Back Up Instrumentation with Primary Systems

Principle

Correlation of patient samples between analyzers is performed to check the accuracy and precision of each analyzer.

Policy

It is the policy of Southeast Arizona Medical Center Laboratory to run correlations between each primary analyzer and its corresponding back-up system twice a year. The following is a list of those analyzers:

Primary	Back-Up
HMX	ACT-5
ACL 8000	ACL 1000
DXC600	CX3
Polyme deo Sedimat 15	Excyte 10

Procedure

1. Choose 5-7 patient samples covering the ranges of low, normal and high.
2. Run samples on HMX, ACL 8000 and DXC600,
3. Run samples on ACT-5, ACL 1000 and CX3.
4. Compare results for any deviations. Document any troubleshooting action.
5. Notify Lab Manager of any problems.
6. Results should be given to Lab Manager for evaluation.
7. LV % for each analyte should be 90% acceptance.

Criteria for Manual Blood Smear Review

A manual differential should be performed if any of the following conditions exist: and remits entered into the opos system using the test code manditt, results are also recorded in the instrument result form.

Leukocyte count is
less than 2,500/cmm
greater than 15, 000/cmm

Granulocyte % is greater than 85%

Monocyte % is greater than 12%

Eosinophil % is greater than 15%

Reverse Differential (lymphs>gans) except pediatric patients

Vote out on any cell line

Review Ruby Cell-Dyn flag messages and perform a manual slide for morphology if any of the Following conditions exist and remits entered into the Opos system using the last code mandiff.

Abnormal RBC distribution

RDW greater than 16

MCH less than 27

MCV greater than 100

MCV less than 75

Platelet Count <50,000 or > 600,000

Abnormal platelet distribution

Flag for nucleated RBC



Manual Blood Smear

Policy

It is the policy of Cochise Regional Hospital Laboratory to reflex any manual blood smear that exceeds the criteria for manual blood smear review. According to Medicare reimbursement clinical reflexing will not be reimbursed without an order from a doctor. It will be the policy of this laboratory to notify the doctor that a blood smear is indicated. Lab results will then be entered upon receipt of the order for blood smear. Results will also be recorded on the instrument printout.

Principle

The examination of the blood smear is an important part of the hematologic evaluation.

Procedure

Preparation of smear:

1. Place a drop of blood 2 to 3 mm in diameter about 1 cm from the end of a clean dust free slide. Place the slide on a flat surface.
2. With the thumb and forefinger of the right hand hold the end of a second (spreader) slide against the surface of the first at an angle of 30 to 45 degrees and draw it back against the drop of blood until contact is established. Allow the blood to run completely across the end filling the angle between the two slides.
3. Push the "spreader" slide at a moderate speed forward so that the blood spreads evenly on the other side behind the edge of the spread keeping contact between the two until all the blood has been spread into a moderately thin film.
4. Air dry the smear.

Staining the smear:

1. Dip slide in stain for 10 seconds.
2. Dip slide in distilled water (ph 6-7) for 20 seconds or more for darker staining.
3. Air dry.

Performance of Differential

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1. Examine slide under low power. Observe distribution of white cells and choose the area near the thin end where red cells touch but do not overlap.
2. Shift to oil immersion objective and classify each WBC until 100 cells have been counted. Note presence of nucleated RBC's and correct WBC count if necessary.

$$\text{Corrected WBC count} = \frac{\text{WBC} \times 100}{100 + \# \text{ of Nrbc's}}$$

3. Note RBC morphology, estimate of platelet count (adequate, decreased, increased, etc.). When the platelet count is normal 8-20 platelets are noted per high power field.

Procedural Notes and Limitations

A good differential depends on a good slide and proper staining technique. Slides should not be counted if:

- there are ridges, lines or holes
- poor margination
- bluish cast after staining

All abnormalities should be brought to the attention of a supervisor or should be repeated for Pathologist review.

Result Reporting

In order to result a manual differential the technologist must contact the primary or attending physician of the need for the review. Upon receipt of the order the results may be entered into the-114MS^WsreaP^S using the test code. While reflexing the blood smear will still be policy reporting the results will not occur until the order has been received. Manual differentials should not be made on blood tubes older than 24 hours old.

References

1. Clinical Diagnosis and Management by Laboratory Methods, 16th edition, Todd, Sanford and Davidson.
2. Wright-Geimsa Stain label.

Criteria for Referral of Blood Smear to Pathologist

1. Evidence of hemoglobinopathy.
2. Sickle cells or hemoglobin C crystals.
3. Evidence of metabolic disease, systemic disease or deficiency state.
 - a. Teardrops
 - b. Howell Jolly bodies (unless patient has had splenectomy)
 - c. Cabot rings
 - d. Greater than moderate burr cells
4. Differential count abnormalities
 - a. Atypical lymphocytes->20%
 - b. Metamyelocytes and myelocytes->10%
 - c. Lymphocytes>60 if >10 years; >80 if < 10 years
 - d. Monocytes->20%
 - e. Eosinophil->15%
 - f. Basophil->8%
 - g. Promyelocyte and blasts- any
5. Plasma cells in peripheral blood.
6. Any unidentified cells.
7. Any physician request for pathologist evaluation.

Send 2-3 unstained slides with a copy of the CBC report to the pathologist.



LABORATORY

Title: Autozero Westergren Erythrocyte Sedimentation Rate (ESR) by Sediplast®
Date: August 20, 2013

Reviewed by _____ Date: _____

Principle:

A pipette (tube) is filled with 1.0 mL of anticoagulated (EDTA) blood and allowed to stand for a period of one hour. After one hour, a reading is taken at the plasma meniscus. This reading represents the distance in mm from the zero mark on the tube and is equal to the Erythrocyte Sedimentation Rate.

Materials

1. Fixed bore pipettes, with self-zeroing cap.
2. Vials
3. Timer

Test Procedure

1. Assemble and check for integrity of supplies. Remove the pink stopper on the prefilled vial (0.2 ml of 3.8% Sodium Citrate is used as diluent). Using a transfer pipette, fill the vial to the bottom of the indicated fill line, with 0.8 ml of blood to make the required dilution ratio.
2. Replace pink pierceable stopper and gently invert several times to obtain homogeneous mixing.
3. Place vial in its rack on a level counter surface free from vibration.
4. The diaphragm of the pink stopper is calibrated to break under the light pressure made by inserting the pipette.
5. Carefully insert the pipette through the pierceable stopper and gently push downwards until the pipette comes into contact with the blood sample. Next, while holding the middle of the pipette, gently twist the pipette and push downwards until the pipette rests on the bottom of the vial.
6. The pipette will autozero the blood and any reasonable excess will flow into the reservoir compartment.
7. To ensure proper results, it is essential that the pipette makes firm contact with the bottom of the vial.

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8. Let sample stand for exactly one hour and then read the numerical results of the erythrocyte sedimentation rate in millimeters.
9. Dispose of properly after use.

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Interpretation of Results

MALE: (under 50) 0-15 mm/hr -(over 50) 0-20 mm/hr

FEMALE: (under 50) 0-20 mm/hr —(over 50) 0- 30 mm/hr

Quality Control

Normal and Abnormal reacting quality control material is available in the laboratory. Controls are tested once each day of use and patient results are not reported until quality control results are within published acceptable limits.

References Polymedco Sediplast® user manual. Cortland Manor, New York.

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Cell Count

Principle

Normal CSF is crystal clear with viscosity comparable to water. There are many conditions which cause the CSF to change in turbidity and viscosity. Cell counts are performed to provide the physician with the necessary information to diagnose these conditions.

Reagents and Equipment

Hemocytometer

Pasteur pipette

saline

Procedure

1st tube – Chemistry

2nd tube – Hematology

3rd tube – Microbiology

4h tube – Serology/Cytology

1. Mix the CSF in tube 3 well.
2. Fill both sides of the hemocytometer with undiluted CSF.
3. Allow the hemocytometer to settle for 10 minutes.
4. Count all red and white blood cells in the 9 large squares on each side of the chambers.

Procedural Notes and Limitations

If there are too many cells present to count dilute the CSF 1:1 with saline before filling chamber. (Additional serial dilutions may be needed). If greater than 5 WBC/cu mm are seen a differential must be done.

Calculations

number of cells counted x dilution = cells/cu mm
.9

OR

number of cells counted x dilution x depth (10) = cells/cu mm
number of squares counted (9)

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Expected Values

Adults — 0-5 cells/cu mm

Neonates — 0- 20 cells/cu mm

Result Reporting

In the HMS system the technologist will enter the results for both white and red blood cells using the test code CSFCELLS.

References

Clinical Diagnosis and Management by Laboratory Methods 17th Edition, p. 463-464
Spinal Fluid Procedure - <http://www.pathguy.com/lectures/csf.htm>.



Operation of the SYSMEX CA-500 Coagulation Analyzer.

The Sysmex CA-500 is an automated Blood Coagulation analyzer fully automated capable of 5-parameter random analysis for in vitro analysis. This instrument has the capability to analyze 10 regular samples, and also one Stat giving us the opportunity of running everything at the same time. Moreover, it allows analyzed data to be display and printed out together with reaction curves, thus making it possible to obtain highly reliable results.

MAINTENENCE

Daily : Daily maintenance must be started at the beginning of every day, before quality control and patient analysis. It must be done on the following order:

- 1- Turn off and on the Sysmex CA-500.
- 2- Empty tube trash box located at the right side. Also empty **the waste** container.
- 3- Replenish water container with Deionized water.
- 4- Check all supplies and refill everything with fresh reagents; CA-CLEAN must be changed every 24 hrs., Buffer every 8 hour shift.
- 5- Perform probe rinse. If visible residue, wipe probe with 70% alcohol.
- 6- Wipe condensation from reagent cooler.
- 7- Check the trap chamber and drain, if needed.
- 8- Check temperatures.

Monthly Maintenance:

- 1- Replace reagent Bottles.

Quarterly Maintenance:

- 1- Clean diH₂O Rinse bottle with alcohol.
- 2- Perform LED calibration.

Yearly Maintenance:

- 1- Replace Rinse Filter/Rinse and prepare

As needed Maintenance:

- 1- Replace fuse
- 2- Perform "Rinse and Prepare"
- 3- Perform maintenance rinse.
- 4- Clean instrument surface.

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DAILY QUALITY CONTROLS

Two levels of ci-Trol Should be run every 8 hours shift for PT and aPTT tests.
Two levels of Innovance D-dimer Should be run every 8 hours when there are specimens to be run.

OPERATION OF SYSMEX CA-500

- 1- Go to the main menu.
- 2- Place sample in the rack with the barcode facing outward if the specimen does not have barcode input the specimen id by pressing the ID No. Entry icon which gives the numeric keyboard, then select the test desire to be run and press START, then press continue to start running the specimen.
- 3- When the analyzer finishes the run automatically the result is printed.



Urinalysis Quality Control

A. General

KOVA-trol Normal and Abnormal urine controls should be used each day for the urine dipsticks. Controls need to be run for confirmatory tests when the tests are performed. Expected values are posted in the laboratory.

B. Out of Control QC

1. Check expiration date of controls and reagents.
2. Repeat test with new control.
3. If still not expected results, repeat with new dipstick or reagent.
4. Record corrective action on worksheet.

Clintek Status

Principle:

Clinitek status Urine chemistry analyzer is a portable instrument for reading traditional Bayer Reagent Strips for Urinalysis. Refer to the bottle label or carton for the tests that are included with each product. The analyzer can also report the color of the urine sample. No special training is needed to use the instrument.

Materials :

1. Multistix Pro
2. Paper Towel (for blotting) .

Specimen :

Random Urine

Quality control :

Positive and Negative control solutions should be tested on a regular basis . This provides a check to ensure that the test strips are reacting properly and the instrument is reading strips properly. Testing controls also helps detect errors caused by incorrect user technique. Prepare the control solutions as instructed in the package insert that comes with control product. Then test the control solution using the same procedure as you use when testing patient urines.

Record the controls results . If any results are not within the expected range, notify the lab supervisor or physician. Refer to the bottle label and / or package insert for storage information and expiration date.

You should test controls:

1. At the start of the day:
2. When you open a new bottle of test strips.
3. Whenever test results are in doubt:
4. When training instrument operators.

Procedure :

Routine Urines . The urine specimen should be fresh , well- mixed, and uncentrifuged. If the urine depth is less than about 3 inches pour the specimen into a narrow tube,such as a **URIN-TEK** Specimen tube .

1. **DIP A BAYER REAGENT STRIP** into the urine . Be sure ALL the test pads are wet
2. **Immediately Remove** the reagent strip from the urine, dragging the edge of the strip against the side of the container as you remove the strip, **At The SameTime , press** either green (Start) key . You now have 10 seconds to complete Steps 3 and 4 .
3. **Blot** the strip to remove excess urine by **Touching the edge** to a paper towel. Do not drag the strip across the towel : touch the edge only .
4. **Place** the Reagent Strip . **With the test pads facing up**, into the middle trough of the test strip table until it touches the **end** of the trough.
5. The table is automatically pulled into the instrument for reading . Results are available in one minute. Be sure not to move or bump the table .

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Complete Urinalysis

Principle:

The examination of urine is performed in three steps. The first step involves evaluation of the physiochemical characteristics of the urine sample. The second step involves the chemical examination of the urine specimen and the third step is the microscopic examination of the urine sediment by trained laboratory personnel.

Materials:

1. Specimen collection device as supplied in the laboratory.
2. Urine centrifuge tubes as supplied in the laboratory.
3. Bayer 10 SG Urine Dipsticks as supplied in the laboratory.
4. Microscope as supplied in the laboratory.
5. Slides and cover slips as supplied in the laboratory.
6. Centrifuge as supplied in the laboratory.

Specimen:

The specimen of choice for this procedure is a fresh (mid-stream or clean catch) specimen, early morning samples are recommended, collected into a clean, dry container. Samples may be stored for 1 hour before testing at room temperature then must be refrigerated at 2-8° C for up to 24 hours.

Quality Control:

Quality control testing for this procedure is outlined in the "UA dipstick" procedure for biochemical dipstick testing found elsewhere in this manual. Proficiency testing supplied to prove competency for identification of formed elements found in a urine specimen are supplied on a quarterly basis.

Remedial Action:

In the event that a member of the laboratory staff cannot prove his competency with proficiency testing, that staff member will take part in an educational in service meant to increase his/her skills in identifying the formed elements of the urine specimen.

Procedure:

1. Obtain a properly labeled urine specimen.
2. Pour off 12 ml of urine into a separate centrifuge tube.
3. Perform a dipstick examination as described in the "UA Dipstick" procedure found elsewhere in this manual.
4. If blood, leukocyte esterase, protein (greater than a trace) or nitrite are positive, a microscopic examination is required. If the listed tests are negative, even though other tests are positive, a microscopic examination need not be performed or performed upon physician request.
5. Centrifuge the 12 ml sample of urine for two (2) minutes in the urine centrifuge.
6. Decant all but 1 ml of the sample.
7. Mix the 1 ml sample well and place one (1) drop of the concentrated urine onto a clean dry slide. Cover with a cover slip as supplied in the laboratory.
8. Perform a microscopic examination of the urine sample.

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Interpretation of Results:

The slide is first examined under low power magnification to locate casts and elements that are present in only a few fields. Casts tend to congregate near the edges of the cover slip. After the entire slide has been scanned, a further examination is made under high power magnification in order to identify specific types of cells, crystals, elements and objects present in the urine and to delineate the various types of casts. A minimum of 10 to 15 high power fields should be scanned for this examination. Good technique requires varying the intensity of the light source of the microscope in order to correctly identify the various components of the sediment. Some elements are more easily recognized in subdued light, others in brighter light.

Red blood cells, leukocytes and epithelial cells are conventionally reported in terms of cells per high power field; casts are counted per low power field. For each determination, the number of elements seen in at least 10 fields should be counted and the average number used for the reported value. Other elements, such as bacteria, parasites, crystals and spermatozoa are usually reported as well.

In this laboratory, results are reported as one of the following for each category:

Appearance:	Color	Formed Elements
CLEAR	STRAW	TRACE
SLT HAZY	LT YELLOW	1+
HAZY	YELLOW	2+
TURBID	DK YELLOW	3+
CLOUDY	ORANGE	4+
	RED	RARE
	BROWN	FEW
		2-4
		5-10
		10-20
		20-50
		>50
		NEGATIVE
		POSITIVE

EXPECTED RESULTS:

- Red Blood Cells: The finding of more than one or two red blood cells per high power field is an abnormal condition. It can indicate a variety of renal and systemic diseases, including trauma to the kidney. It may also be found following violent exercise. It may follow traumatic catheterization, the passage of stones or contamination from menstrual blood. Hematuria occurs with pyelonephritis, tuberculosis of the genitourinary tract, cystitis, prostatitis, renal calculi, renal tumors and other malignancies of the urinary tract, and hemorrhagic diseases such hemophilia, etc. Red blood cells will tend to lyse or dissolve if allowed to stand in urine which is alkaline or dilute.
- White Blood Cells: The presence of large numbers of white blood cells (leukocytes) usually indicates bacterial infection in the urinary tract.

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Pyuria may also be seen in acute glomerulonephritis. The cells are segmented neutrophils or "polys". Large amounts of mononuclear cells "Lymphs", in a patient with a kidney transplant may indicate early tissue rejection phenomena. Epithelial Cells: Large numbers of renal epithelial cells may indicate active tubular degeneration. These cells are noted in the urine of patients with acute tubular necrosis and necrotizing papillitis. Squamous epithelial cells appear frequently in normal urine.

- Crystals: The type and quantity of crystalline precipitate vary with the pH of the urine. Amorphous material is of little importance. Crystals in normal urine are formed as the specimen cool. Crystals of abnormal urine cystine, leucine and tyrosine and cholesterol. The following table lists some crystals found in urine sediment and the physical-chemical characteristics associated with them.

INORGANIC SEDIMENT:

ACID URINE

SOLUBILITY

NAME	COLOR	SHAPE	ALK	ACID	ALCOHOL	"C	OTHER
Amorphous urates	Brick-Red	Granules				80 °C	= Acetic Acid
Uric Acid	Yellow-Brown	Polymorphous—whetstones, rosettes of prisms, rhombohedral prisms, hexagonal plate					
Sodium urate	Colorless to Yellow	Fan of slender prisms	+	-		80°C	
Cystine (rare)	1) Colorless 2) Highly retractile	Flat hexagonal plates with well-defined edges Singly or in clusters	+	+			
Cholesterol (rare)	1) Colorless 2) Highly retractile	"Broken window panes" with notched corners Flat plates	-	-			Ether Chloroform
Leucine (rare)	1) Yellow or Brown 2) Highly retractile	Spheroids with striations Pure form hexagonal		4-	-		Slightly In hot H ₂ O
Tyrosine (rare)	Colorless or Yellow	Fine silky needles in sheaves or rosettes	+	+			
Bilirubin Brown	Reddish	Cubes Rhombic plates Amorphous needles	+	+	-	80°C	Acetone Chloroform

ACID, NEUTRAL, OR SLIGHTLY ALKALINE URINE

Calcium oxalate	Colorless	Octahedral Dumbbells Often small—use h.p.	- +		Dilute
Hippuric acid	Colorless			-	HCl

ALKALINE, NEUTRAL, OR SLIGHTLY ACID URINE

Triple phosphate	Colorless	"Coffin lids" 3-6 sided prism Occ. fern-leaf	-	-	Dilute Acetic Acid
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ALKALINE URINE

Calcium carbonate	Colorless	Needles Spheres Dumbbells		- - -	Acetic Acid
Ammonium Writs	Yellow Opaque Brown	"Thorn apple" spheres Rhombic plates Four sided prisms	Dumbbells	60°C with Sheaves of needles Acid	
Calcium phosphate	Colorless	Prisms Plates Needles		Dilute - - -	Acetic Acid

- **Bacteria:** Normal urine contains no bacteria. If proper and careful technique was used to obtain the sample and if the specimen was protected from contaminants before examination, the presence of bacteria in significant numbers may indicate urinary tract infection. The presence of leukocytes helps to differentiate between "contamination" and a "true Infection".
- **Yeast and Parasites:** Yeast cells (*Candida albicans*) may be indicative of urinary moniliasis, especially in patients with diabetes mellitus. Frequently, yeast appears as a contaminant in the urine of female patients with vaginal moniliasis. The majority of parasites observed in urine are contaminants from fecal or vaginal material. A urinary tract parasite infestation may be associated with the presence of red blood cells, as in *Schistosoma haematobium*.
- **Spermatazoa:** Spermatazoa are frequently seen in urine following nocturnal emissions or sexual intercourse.
- **Casts:** Cast formation occurs usually in the distal convoluted tubule of the nephron. Casts may also occur in the ascending loop of Henle or the collecting duct. Requirements for cast formation are an acid condition, high salt concentration, reduced urine flow and protein. Casts are named according to the matrix of the inclusions contained in them, e.g., red blood cell cast, white blood cell cast, etc.
 - Red Blood Cell Casts indicate the presence of an acute inflammatory or vascular disorder in the glomerulus causing renal hematuria. They should always be regarded as pathological and may be the only manifestation of acute glomerulonephritis, renal infarction, collagen disease, or kidney involvement in subacute bacterial endocarditis.
 - White Blood Cell Casts may be found in the urine from patients with acute glomerulonephritis, nephrotic syndrome or pyelonephritis. Since pyelonephritis may remain completely asymptomatic even though it is progressively destroying renal tissue, careful examination of the urinary sediment for leukocyte casts is important. In some cases, it may be the only significant laboratory finding in an asymptomatic situation.
 - Epithelial Cell Casts are formed by fused desquamated tubular cells. Since the tubule is a living membrane, it is always replacing itself. Thus, the finding of an occasional renal epithelial cell or clump is not remarkable. However, in any disease producing damage to tubular epithelium, the appearance of many casts may indicate excessive desquamation such as may occur in nephrosis, eclampsia, amyloidosis and in the presence of poisoning with heavy metals and a variety of other toxins.
 - Hyaline Casts are formed of the gel of Tamm-Horsfall protein. The presence of hyaline casts imply damage to the glomerular capillary membrane, permitting leakage of proteins through the glomerular filter. Such damage may be permanent or transient as a result of fever or the effects of posture (orthostatic, iordotic), emotional stress or strenuous exercise.
 - Granular Casts: The terms "coarsely granular" and "finely granular" are merely descriptive, indicating the degree of degeneration that has occurred in the cellular inclusion-the cells having been broken down into coarse or finer particles. While an occasional granular cast may be found in normal individuals, their presence beyond "occasional cast" may indicate pyelonephritis. Granular casts are also found in chronic lead intoxication.
 - Waxy and Fatty Casts are associated with tubular inflammation and degeneration. The broad, waxy cast is formed in the collecting tubules when the urine flow them is reduced. Both waxy and fatty casts are found in chronic renal disease.



Reporting of Patient Results:

Patient results are entered into the LIS using the above table for reporting of results.

Inoperable Test System:

In the event that complete urinalysis testing cannot be performed, samples be sent to the Copper Queen Hospital.

Clinical Significance:

The benefit of performing complete urinalysis examination is well known as a means to assess kidney function.

References:

Modern Urine Chemistry. 1982, Ames Company, Elkhardt, Indiana.

Urinalysis (MultiStix 10 SG)

Principle:

The MultiStix SG Reagent strips for Urinalysis are firm plastic strips to which are affixed several separate reagent areas. The reagent test areas on the Reagent Strips are ready to use upon removal from the bottle and the entire reagent strip is disposable. The following are chemical principles of the reagent areas.

1. Glucose: This test is based on a double sequential enzyme reaction. One enzyme, glucose oxidase, catalyzes the formation of gluconic acid and hydrogen peroxide from the oxidation of glucose. A second enzyme, peroxidase, catalyzes the reaction of hydrogen peroxide with a potassium iodide chromogen to oxidize the chromogen to colors ranging from green to brown
2. Bilirubin: This test is based on the coupling of bilirubin with diazotized dichloroaniline in a strongly acid medium. The color ranges through various shades of tan.
3. Ketone: This test is based on the development of colors ranging from buff-pink, for a negative reading, to purple when acetoacetic acid reacts with nitroprusside.
4. Specific Gravity: This test is based on the apparent pKa change of certain pretreated polyelectrolytes in relation to ionic concentration. In the presence of an indicator, colors range from deep blue-green in urine of low ionic concentration through green and yellow-green in urines of increasing ionic concentration.
5. Blood: this test is based on the peroxidase-like activity of hemoglobin, which catalyzes the reaction of diisopropylbenzene dihydroperoxide and 3,3",5,5"-tetramethylbenzidine. The resulting color ranges from orange through green; very high levels of blood may cause color development to continue to blue.
6. pH: The test is based on the double indicator principle that gives a broad range of colors covering the entire urinary pH range. Colors range from orange through yellow and green to blue.
7. Protein: This test is based on the protein-error-of-indicators principle. At a constant pH, the development of any green color is due to the presence of protein. Colors range from yellow for "Negative" through yellow-green and green to green-blue for "Positive" reactions.
8. Urobilinogen: This test is based on a modified Ehrlich reaction, in which *p*-diethylaminobenzaldehyde in conjunction with a color enhancer reacts with urobilinogen in a strongly acid medium to produce a pink-red color.
9. Nitrite: This test depends upon the conversion of nitrate (derived from the diet) to nitrite by the action of Gram negative bacteria in the urine. At the acid pH of the reagent area, nitrite in the urine reacts with *p*-arsanilic acid to form a diazonium compound. This diazonium compound in turns couples with 1,2,3,4-tetra-hydrobenz(h)quinolin-3-ol to produce a pink color.
10. Leukocytes: Granulocytic leukocytes contain esterases that catalyze the hydrolysis of the derivatized pyrrole amino acid ester to liberate 3-hydroxy-5-phenyl pyrrole. This pyrrole then reacts with a diazonium salt to produce a purple product.

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Materials:

1. MultiStix 10 SG as supplied in the laboratory. Product is stable until the expiration date printed on the container label when stored at room temperature between 15-30° C. Do not store the container in direct sunlight. All unused strips must remain in the original container after opening. Do not remove the desiccant(s) from the container. Do not remove the strip from the container until immediately before it is to be used for testing. Replace the cap immediately and tightly after removing the reagent strip. Do not touch the test areas of the reagent strip. Work areas and specimen containers should be free of detergents and other contaminating substances.
2. Specimen collection device as supplied in the laboratory.
3. Cleansing wipes as supplied in the laboratory for performing a "Clean Catch" collection.

Specimen:

The specimen of choice for this procedure is urine collected in a clean container and tested as soon as possible. Do not centrifuge. The use of urine preservatives is not recommended. If testing cannot be performed within an hour after voiding, the specimen may be refrigerated for up to 24 hours before testing. Allow the specimen to warm to room temperature if refrigerated.

Nitrite test results are optimized by using a first morning specimen or one that has incubated in the bladder for four (4) hours or more. It is especially important to use fresh urine to obtain optimal results with tests for bilirubin or urobilinogen, as these compounds are very unstable when exposed to room temperature and light.

Prolonged exposure of urine to room temperature may result in microbial proliferation with resultant changes in pH. A shift to alkaline pH may cause false positive results with the protein with the protein test area. Urine containing glucose may decrease in pH as organisms metabolize the glucose. Bacterial growth from contaminating organism may cause false positive blood reactions from the peroxidases produced. In random urine urine specimens from females, a positive result for leukocytes may be due to a source external to the urinary tract.

Contamination of the urine specimen with skin cleansers containing chlorhexidine may affect protein (and to a lesser extent specific gravity and bilirubin) test results. The user should determine whether the use pf such skin cleansers is warranted.

Quality Control:

Known positive and negative specimens are supplied in the laboratory for quality control testing. Known positive and negative specimens are tested once each day of use in the same manner as patient samples are tested. Water should not be used as a negative control. Patient results are never reported until acceptable results are obtained form quality control testing.

Remedial Action:

In the event that quality control testing does not produce acceptable results, the following procedure may be used to correct any deficiencies.

1. Repeat the testing being careful to follow incubation times exactly.
2. Reconstitute new control material and repeat testing.
3. Obtain a new vial of test strips and repeat testing.
4. Contact the Laboratory Manager.

Procedure:

1. Collect a fresh urine specimen in a clean, dry container. Mix well immediately before testing.
2. Remove one strip from the container and replace cap.
3. Completely immerse the reagent areas of the strip in the urine sample and remove immediately to avoid dissolving out reagents.
Note: An alternate method of applying the sample is to use a clean disposable pipet to dispense the urine specimen onto the reagent pads, one drop to a pad.
4. While removing the strip from the specimen, run the edge of the entire length of the strip against the rim of the urine container to remove excess urine.
5. Hold the strip in a horizontal position to prevent possible mixing of chemicals from adjacent reagent areas and/or contaminating the hands with urine and touch one side to a clean paper towel to remove excess urine.
Note: If the sample has been applied with a pipet, turn the strip on one side against a clean paper towel to remove excess urine.
6. Compare the reagent areas to the corresponding Color Chart on the container at the times specified. Hold the strip close to the color blocks and match carefully. Avoid laying the strip directly on the Color Chart, as this will result in the urine soiling the chart.

Proper read time is critical for optimal results. Read the glucose and bilirubin tests at 30 seconds after dipping. Read the ketone test at 40 seconds; the specific gravity test at 45 seconds; pH, protein, urobilinogen, blood and nitrite at 60 seconds; and leukocytes at 2 minutes. The pH and protein areas may also be read immediately or at any time up to 2 minutes after dipping.

After dipping the strip, check the pH area. If the color on the pad is not uniform, read the reagent area immediately, comparing the darkest color to the appropriate Color Chart. All reagent areas except leukocyte may be read between 1 and 2 minutes for identifying negative specimens and for determination of the pH and SG. A positive reaction (Small or greater) at less than 2 minutes on the leukocyte test may be regarded as a positive indication of leukocytes in urine. Color changes that occur after 2 minutes are of no diagnostic value.

Interpretation of Results:

Results with Bayer Reagent strips are obtained in clinically meaningful units directly from the Color Chart comparison.

Limitations:

1. As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single result or method.
2. Substances that cause abnormal urine color, such as drugs containing azo dyes (e.g., Pyridium, Azo Gantrisin, Azo Gantanol), nitrofurantoin (Macrodantin, Furadantin), and riboflavin, may affect the readability of the reagent areas on urinalysis reagent strips. The color development on the reagent pad may be masked, or a color reaction may be produced on the pad that could be interpreted visually as a false positive.
3. Glucose: Ascorbic acid concentrations of 50 mg/dL or greater may cause false negatives for specimens containing small amounts of glucose (75-125 mg/dL). Ketone bodies reduce the sensitivity of the test; moderately high ketone levels (40 mg/dL) may cause false negatives for specimens containing small amounts of glucose (75-125 mg/dL) but the combination of such ketone levels and low glucose levels is metabolically improbable in screening. The reactivity of the glucose test decreases as the SG of the urine increases. Reactivity may also vary with temperature. This test is specific for glucose; no substance excreted in urine other than glucose is known to give a positive test. The reagent area does not react with lactose, galactose, fructose nor reducing metabolites of drugs (e.g., salicylates and nalidixic acid).

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4. Bilirubin: Indican (indoxyl sulfate) can produce a yellow-orange to red color response that may interfere with the interpretation of a negative or a positive bilirubin reading. Metabolites of Lodine (etodolac) may cause false positive or atypical results; ascorbic acid concentrations of 25 mg/dL or greater may cause false negatives. Since very small amounts of bilirubin may be found in the earliest stages of liver disease, the user must consider whether the sensitivity of the reagent strip to bilirubin is sufficient for the intended use. When very small amounts of bilirubin in urine are sought (e.g., earliest phase of hepatitis), ICTOTEST reagent tablets should be the method of choice
5. Ketone: False positive results (Trace or less) may occur with highly pigmented urine specimens or those containing large amounts of levodopa metabolites. Compounds such as mesna (2-mercaptopropane sulfonic acid) that contain sulphydryl groups may cause false positive results or an atypical color reaction. This test reacts with acetoacetic acid in urine, it does not react with acetone or 3-hydroxybutyric acid.
6. Specific Gravity: The chemical nature of the reagent test strips may cause slightly different results from those obtained with other specific gravity methods when elevated amounts of certain urine constituents are present. Highly buffered alkaline urines may cause low readings relative to other methods. Elevated specific gravity readings may be obtained in the presence of moderate quantities of protein (100-750 mg/dL).
7. Blood: Elevated specific gravity may reduce the reactivity of the blood test. Capoten may also cause decreased reactivity. Certain oxidizing contaminants, such as hypochlorite, may produce false positive results. Microbial peroxidase associated with urinary tract infections may cause false positive reactions. Levels of ascorbic acid normally found in urine do not interfere with this test.
8. pH: If proper procedure is not followed and excess urine remains on the strip, a phenomenon known as "runover" may occur, in which the acid buffer from the protein reagent will run onto the pH area, causing a false lowering of the pH result.
9. Protein: False positive results may be obtained with highly buffered or alkaline urines. Contamination or the urine specimen with quaternary ammonium compounds (e.g., from some antiseptics and detergents) or with skin cleansers containing chlorhexidine may also produce false positive results. The reagent area is more sensitive to albumin than to globulins, hemoglobin, Bence-Jones proteins and mucoprotein; a negative result does not rule out these other proteins.
10. Urobilinogen: The reagent area may react with interfering substances known to react with Ehrlich's reagent, such as p-amino-salicylic acid and sulfonamides. Atypical color reactions may be obtained in the presence of high concentrations of p-amino-benzoic acid. Strip reactivity increases with temperature; the optimum temperature is 22-26° C. The test is not a reliable method for the detection of porphobilinogen. The absence of urobilinogen cannot be determined with this test.
11. Nitrite: Pink spots or pink edges should not be interpreted as a positive result. Any degree of uniform pink color development should be interpreted as a positive result suggesting the presence of 100,000 or more organisms per mL, but color development is not proportional to the number of organisms present. A negative result does not in itself prove that there is no significant bacteriuria. Negative results may occur when urinary tract infections are caused by organisms that do not contain reductase to convert nitrate to nitrite; when urine has not been retained in the bladder long enough (four hours or more) for reduction of nitrate to nitrite to occur; or when dietary nitrate is absent, even if organisms containing reductase are present and bladder incubation is ample. Sensitivity of the nitrite test is reduced for urines with high specific gravity. Ascorbic acid concentrations of 25 mg/dL or greater may cause false negative results with specimens containing small amounts of nitrite ion (0.06 mg/dL or less).

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12. Leukocytes: Elevated glucose concentrations (> 3 g/dL) or high specific gravity may cause decreased test results. The presence of cephalexin (Keflex, cephalothin (Keflin), or high concentrations of oxalic acid may also cause decreased test results. Tetracycline may cause decreased reactivity, and high levels of the drug may cause false negative reaction.

Expected Values:

Expected values for the typical "normal" healthy population and the abnormal population are listed below for each reagent.

1. Glucose: Small amounts of glucose are normally excreted by the kidney. These amounts are usually below the sensitivity of this test. Results at the first positive level may be significantly abnormal if found consistently.
2. Bilirubin: Normally no bilirubin is detectable in urine by even the most sensitive of methods. Even trace amounts of bilirubin are sufficiently abnormal to require further investigation. Atypical colors (colors unlike the negative or positive color blocks shown on the Color Chart) may indicate that bilirubin-derived bile pigments are present in the urine sample and may be masking the bilirubin reaction. These colors may indicate bile pigment abnormalities and the urine specimen must be tested further with a confirmative test such as the ICTOTEST.
3. Ketone: Normal urine specimens ordinarily yield negative results with this reagent. Detectable levels of ketone may occur in urine during physiological stress conditions such as fasting, pregnancy and frequent strenuous exercise. In ketoacidosis, starvation or with other abnormalities of carbohydrate or lipid metabolism, ketones may appear in urine in large amounts before serum ketone concentrations are elevated.
4. Specific Gravity: Random urines may vary in specific gravity from 1.001 — 1.035. Twenty-four hour urines from normal adults with normal diets and normal fluid intake will have specific gravity of 1.016 — 1.022.
5. Blood: The significance of the Trace reaction may vary among patients, and clinical judgment is required for assessment in an individual case. Development of green spots (intact erythrocytes) or green color (free hemoglobin/myoglobin) on the reagent area within 60 seconds indicates the need for further investigation. Blood is often, but not always, found in urine of menstruating females. The test is highly sensitive to hemoglobin and thus complements the microscopic examination.
6. pH: Both the normal and abnormal urinary pH range is from 5 to 9.
7. Protein: Normally no protein is detectable in urine, although a minute amount is excreted by the normal kidney. A color matching any block greater than Trace indicated significant proteinuria. For urine of high specific gravity, the test area may most closely match the Trace color block even though only normal concentrations of protein are present. Clinical judgment is needed to evaluate the significance of Trace results.
8. Urobilinogen: The normal urobilinogen range obtained with this test is 0.2-1.0 mg/dL (1 mg is approximately equal to 1 Ehrlich Unit/dL). A result of 2.0 mg/dL represents the transition from normal to abnormal, and the patient and/or urine specimen should be evaluated further.
9. Nitrite: Normally no nitrite is detectable in urine. The proportion of positive nitrite tests in cases of significant infection depends on how long the urine specimens



were retained in the bladder prior to collection. Identification of known positive cases with the nitrite test ranges from as low as 40%, when little bladder incubation occurred, to as high as approximately 80%, when a minimum of four hours of bladder incubation occurred.

Leukocytes: Normal urine specimens generally yield negative results; positive results (Small or greater) are clinically significant. Individually observed Trace results may be of questionable clinical significance; however, Trace results observed repeatedly may be clinically significant. Positive and repeated Trace results indicate the need for further testing of the patient and/or urine specimen, according to medically accepted procedures for pyuria. Positive results may occasionally be found with random specimens from females due to contamination of the specimen by vaginal discharge.

Reporting of Patient Results:

Dipstick urine results are reported by means of the LIS. Reporting is performed by the input of the levels obtained from the reagent strip.

Inoperable Test Conditions:

In the event that Reagent Strips are unavailable for testing, the sample will be spun down and a microscopic examination will be made. Clinitest tablets, IctoTest, AceTest and a Refractometer are available for use as backup biochemical testing.

Clinical Significance:

The benefit of reagent strip testing as aid to provide information regarding the status of carbohydrate metabolism, kidney and liver function, acid-base balance and urinary tract infection is well documented.

References:

Bayer Multisick 10 SG package insert, 4/99, Bayer Corporation, Elkhart, IN.

Sulfosalicylic Acid Confirmatory Test for Protein

Principle

Sulfosalicylic acid tests for both albumin and globulin. It is a simple precipitation test that in the presence of protein turns a clear urine specimen to turbid. Changes in urinary solute concentrate effect the Chemstrip results but not the sulfosalicylic acid method.

Quality Control

Normal and Abnormal KOVA - trol should be performed when confirmatory testing is needed.

Procedure

- A. Using a 12 x 75 test tube, add one part sulfosalicylic acid to one part centrifuged urine and observe for turbidity holding the tube against a white background with black print.
- B. Grade and report as follows:
 1. Neg: no turbidity
 2. trace: slight, distinct turbidity
 3. 1+: definite turbidity, print readable
 4. 2+: light cloud, print readable
 5. 3+: moderate cloud, slight precipitate
 6. 4+: heavy cloud, flocculent

Expected Values

Negative for normal urine

Result Reporting

Log on urinalysis worksheet.

References

Fundamentals of Clinical Chemistry, 2nd Edition
package insert



Clinitest is not specific for glucose and will react with urine that contains sufficient quantities of other reducing substances. An example would be galactose. It is important that the physician be notified when the Clinitest is positive, but the urine dipstick is negative.

Result Reporting

Log on urinalysis worksheet

Reference

Clinitest Reagent tablet insert, September 1995

Ictotest Confirmatory Test for Bilirubin

Principle

Ictotest reagent tablets are used to test for the presence of bilirubin in urine. The presence of bilirubin is an important finding in the evaluation of liver function.

Reagents and Equipment

absorbent test mat
Ictotest reagent tablet
transfer pipet
DI water

Quality Control

Normal and Abnormal KOVA-trol should be performed when confirmatory testing is needed.

Procedure

1. Place a square of the absorbent test mat supplied onto a paper towel. Place 10 drops of urine onto the center of the test mat.
2. Shake one ICTOTEST Reagent Tablet into the bottle cap and transfer the tablet to the center of the moistened mat. Do not handle tablet with the fingers. Recap the bottle promptly.
3. Place one drop of water onto the tablet. **Wait 5 seconds**, then place a second drop of water onto the tablet so that the water runs off tablet onto the mat.

Expected Values

Negative for normal urine

Procedural Notes and Limitations

The presence of a blue or purple color on the mat indicates that bilirubin is present. A slight pink or red color should be ignored.

Metabolites of Phridium give bright red-orange colors which may mask the reaction of small amounts of bilirubin. Elevated concentrations of urobilinogen do not mask the reaction of small amounts of bilirubin, but atypical orange colors are produced. Chlorpromazine in large amounts may give a false positive result, and metabolites of Lodine (etodolac) may cause false positive or atypical results.



Result Reporting

Log on urinalysis log.

Referenced:

Icotest package insert, September 2009

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Acetest Test for Ketone or Acetone (Urine or Serum)

Principle

This test is based on the nitroprusside reaction with Ketone bodies to give a purple color. The presence of Ketone bodies is important in the evaluation of carbohydrate metabolism.

Reagents and Equipment

white paper
Acetest tablet

Quality Control

Normal and Abnormal KOVA-trol should be performed when confirmatory testing is needed.

Procedure

1. Remove tablet from bottle and recap promptly. Place tablet on clean, dry, white paper.
2. Put one drop of urine or serum directly on top of tablet.
3. For urine testing- compare color tablet to charts 30 seconds after application of specimen
4. For serum testing- compare color of tablet to color chart two minutes after application of serum.

Expected Values

Ketones are not found in blood or urine in normal patients or normal carbohydrate metabolism.

Result Reporting

Log on urinalysis log

Serum Acetone should be reported as "positive" or "negative" in the Opos computer system.

References

Acetest Package insert, August 2010

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Sure-Vue Serum/Urine Pregnancy Test

Principle:

The Sure-Vue Serum/Urine Pregnancy Test utilizes a combination of monoclonal and polyclonal antibody reagents to selectively detect elevated levels of hCG in serum or urine. The assay is conducted by the addition of a serum or urine specimen into the test device sample well and observing for the formation of colored lines. The specimen migrates via capillary action along the membrane and reacts with the colored conjugate. A positive specimen reacts with the hCG-specific antibody colored conjugate and forms a colored line in the T (test) window. Absence of this colored line suggests a negative result. To serve as a control for the procedure, a colored line in the C (control) window will always appear regardless of the presence or absence of hCG.

Materials:

1. Sure-Vue Serum Pregnancy test device as supplied in the laboratory. The device is stable until the expiration date printed on the package label when stored at room temperature (15-30° C). The test device must remain sealed in the protective pouch until ready for use.
2. Timer
3. Specimen collection container.

Specimen:

Urine:

The specimen of choice for this procedure is a fresh urine specimen collected into a clean, dry container, either plastic or glass. Specimens collected at random may be used, however, the first morning urine generally contains the highest concentration of hormone. A urine sample exhibiting visible precipitates should be centrifuged or allowed to settle before testing. Gross hematuria may prevent an accurate reading of test results by masking the positive line.

Serum:

The specimen of choice for this procedure is blood collected by approved laboratory methods into a sterile tube without any anticoagulants and processed to produce a clear serum specimen. If the serum specimen is cloudy or highly viscous, dilute it with equal parts of saline before testing. Hemolyzed specimens may require a new sample for accurate results. Lipemic specimens may be centrifuged for a short period of time.

Specimen Storage:

Specimens, urine or serum, may be stored at 2-8° C for up to **241 hours** prior to testing. If specimens are refrigerated, they must be equilibrated to room temperature before testing. Serum specimens can be frozen at -20° C for 3 months before testing. Frozen samples must be thawed and mixed before testing.

Quality Control:

Internal Controls:

The appearance of a Control Line in the C region of the device is a positive procedural control. Correct procedural technique, specimen flow and device performance is confirmed when a colored line appears in the C (control) area of the membrane. If the colored line fails to appear in the C (control) area, the test result is invalid.

A clear background is an internal negative procedural control. The

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background color should be white to light pink and should not interfere with the reading of the membrane. If a more intensely red background color appears, it may interfere with the ability to read the test result, therefore the test should be repeated.

External Controls:

Urine/Serum positive and negative quality control material is supplied in the laboratory. External quality controls are tested with each new lot or shipment of kits received, every 30 days and as a means of troubleshooting procedural problems.

Remedial Action:

In the event that unacceptable quality control or patient results are obtained, the following procedure is suggested:

1. Obtain a new testing device and repeat the testing carefully following procedural steps.
2. Repeat the testing including quality control material.
3. Obtain a new patient specimen and repeat the testing.
4. Obtain a new package or lot number of testing devices and repeat the testing.
5. Contact the Laboratory Manager.

Patient results are not reported until acceptable quality control results are obtained.

Procedure:

The pouch must be at room temperature before opening to avoid condensation of moisture on the membrane. Allow specimen and/or controls to reach room temperature prior to testing.

1. Remove enough test devices from their protective pouches to perform the necessary testing. Place the devices on a flat surface.
2. Label the devices as necessary with patient or control identification.
3. Dispense 4 drops (approximately 0.15 mL) of specimen into the round sample well.
4. Wait for the colored lines to appear.
5. Read results at 4 minutes. Positive results may be observed in as short as 30 seconds depending on the concentration of hCG. The presence of the Control Line is not indicative of the test being completed. Wait the entire 4 minutes for completion of the test. Read under direct light to avoid interference of shadows in the T and C windows.

Interpretation of Results:

Negative Results:

The test result is negative if a colored line appears only in the C (control) window.

Positive Results:

The test result is positive if one colored line appears in the T (test) window and one colored line appears in the C (control) window. Any colored line in the T (test) window should be considered positive. Colored lines may be lighter or darker than each other. Specimens with hCG levels near the threshold of the test may develop color (faint lines) overtime after the 4 minutes reading. In such cases another test should be performed with a new specimen in 48-72 hours. A line that appears after 15 minutes should be ignored.

Invalid Results:

The test is invalid if no colored line appears in the C (control) window even if a colored line appears in the T (test) window.

Serum:

If no colored line appears in the C (control) window or the migration of the specimen is too slow or incomplete, add 1 to 2 additional drops of serum or add 1 to 2 drops of deionized water or saline into the sample well and wait an additional 4 minutes. If a colored line still does not appear in the C (control) window, the serum could be too

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viscous. Dilute the serum 1:1 with saline or deionized water and repeat the test using another device. Dilution with saline or deionized water to specimens with low levels of hCG will dilute sample lines. Care must be used to read the assay correctly.

Urine:

If no colored line appears in the C (control) window, add 1 to 2 additional drops of urine and wait an additional 4 minutes. If a colored line still does not appear in the C (control) window, the test is invalid and should be repeated using another device.

Expected Values:

Negative results are expected in healthy non-pregnant women and healthy men. Healthy pregnant women have hCG present. The amount will vary with gestational age and between patients. Sure-Vue Serum/Urine hCG can detect hCG levels as low as 25 mIU/mL.

Limitations:

1. False negative results may occur when levels of hCG are below the sensitivity level of the test. When pregnancy is still suspected, a fresh serum or a first morning urine specimen should be collected 48 hours later and tested.
2. Elevated levels of hCG may be found in trophoblastic disease, choriocarcinoma and embryonal cell carcinoma. Islet cell tumors may also produce hCG as well as other carcinomas.
3. Detectable levels of hCG may remain several weeks following normal pregnancy, delivery by cesarean section, or spontaneous or therapeutic abortion.
4. Ectopic pregnancies may produce very low levels of hCG. A negative test, therefore, does not exclude ectopic pregnancy. If this condition is suspected, further testing using a quantitative test may be desirable. Abnormally high levels of hCG may be seen in molar pregnancies. Samples from abnormal pregnancies are beyond the intended use for qualitative hCG tests.
5. Approximately one third of all conceptions end in natural termination. This may produce positive results when testing early in the pregnancy, followed by negative results after the natural termination. Low positive results may be confirmed by retesting with a fresh serum or first morning urine specimen collected 48 hours later.
6. This test provides a presumptive diagnosis for pregnancy. Physicians should evaluate all clinical and laboratory findings before making a definitive diagnosis.
7. A viscous specimen (high specific gravity) may exhibit a slower flow rate, therefore requiring more time for the test to be completed.
8. A high dose "hook effect" may occur where the intensity of sample line decreases as the concentration of hCG increases. If a "hook effect" is suspected, dilution of specimens may increase color intensity of the sample line.
9. This test is designed to be a qualitative test only and does not correlate directly to quantitative hCG tests. The intensity of color in a positive line should not be evaluated as "quantitative or semi-quantitative".
10. Sensitive immunoassays may demonstrate false positive results with specimens containing heterophile antibodies. Assays may also exhibit false positive or false negative results with specimens containing human anti mouse antibodies. These specimens may come from patients receiving preparations of mouse monoclonal antibodies for diagnosis or therapy or have been exposed to mice. If the qualitative interpretation is inconsistent with the clinical evaluation, results should be confirmed by an alternate hCG method.

Reporting of Patient Results:

Patient results are reported as either "Positive" or "Negative" in the LIS.

Inoperable Test System:

In the event that the Sure-Vue Serum/Urine hCG test kit is unavailable, Quantitative BhCG may be performed using the Access Chemistry Instrument supplied in the laboratory.



Clinical Significance:

The detection of hCG (human chorionic gonadotropin) in serum and urine has proven valuable in the presumptive diagnosis of pregnancy.

References:

Sure-Vue Urine/Serum hCG Test Kit insert, 3/03, Fisher Scientific Co., Houston, Texas.

Refractometer

Principle

The Reichert Refractometer is designed for simple and rapid microanalysis of body fluids. The three scale reticle provides read out for urine specific gravity while the remaining scale is calibrated for protein calibration of plasma or serum. The instrument is temperature compensated for temperatures between 60 degrees F (16C) and 100 degrees F (38C). There is no need to adjust reading for either temperature of sample or ambient temperatures.

Materials

- A. Plastic disposable pipette
- B. distilled water
- C. refractometer
- D. sample

Procedure

A. Hold instrument horizontally and swing cover plate up to expose the measuring prism. Clean the prism and bottom surface of cover plate if necessary.

B. Place a drop or two of sample on the prism. Close cover plate immediately.
**NOTE: Do not use glass or metal applicators as they may scratch prism surface.

- or -

Close cover plate and place drop on exposed portion of prism. Drop will be drawn into space between cover plate and prism. Avoid lifting.

C. Hold instrument by placing your finger on the cover plate and press gently, but firmly. This will spread the specimen in a thin layer over prism.

D. Point instrument towards a light source. Tilt until the contrast between light and dark is obtained.

E. The reading should be taken at the point where the dividing line between light and dark fields crosses the scale. (See diagram below). Values can be taken directly from the scale.



Expected Values

Urine specific gravity ranges are 1.005 to 1.030.

Normal Values

Normal values for urine specific gravity ranges are 1.010 to 1.025.

Quality Control

Quality control will be run daily.

Maintenance

- A. Clean with soft cloth or tissue paper moistened with distilled water.
- B. Wipe the prism and bottom surface of cover plate.
- C. Dry with a soft cloth or tissue paper. Erroneous results may occur if surfaces are not cleaned properly.

**NOTE: Do not immerse eyepiece in water. Never use gritty cleaning compounds or very hot water. Do not expose instrument to temperatures above 150 degrees F (60C).



Calibration

The Reichert Refractometer rarely needs adjustment according to manufacturer documentation, however if readjustment is warranted take the following steps:

- A. Temperature of instrument should be between 70 degrees F (21C) and 85 degrees F (29C).
- B. Using distilled water apply sample to prism.
- C. Take reading. If reading departs from 1.000 an adjustment may be made by adjusting the screw at the bottom of instrument. Turning screw first counterclockwise will move the dividing line below 1.000. Turn clockwise to bring back to 1.000. Final adjustment is always clockwise. Do not remove screw from instrument.

Semi-quantitative Confirmatory Testing for Albumin in Urine Using Cargille Kingsbury-Clark Standards and Sulfosalicylic Acid Method

PRINCIPLE

The Kingsbury-Clark standards consist of eight (8) standards which are turbidity suspensions in a gel to represent 5, 10, 20, 30, 40, 50, 75 and 100 mg of albumin as part of a total protein precipitation in 100 ml of urine.

Albumin and other proteins precipitate from urine with a 3% solution of sulfosalicylic acid in a graduated albumin tube. The solution is mixed and compared to the standards after 10 minutes.

The Cargille Kingsbury-Clark standards were developed in order to provide a set of stable standards for visual comparison with urine treated with sulfosalicylic acid. The standards have stepped degrees of turbidity which are compared with the turbidity of the specimen which is caused by the precipitation of protein by the sulfosalicylic acid.

SUMMARY

The Kingsbury-Clark standards rack holds eight (8) standards alternately placed in order to accommodate the urine albumin tube. The black background shows the presence of faint traces of turbidity under opaque back lighting. Critical comparisons are made using the black and white comparison strip.

PROCEDURE (Recommended)

1. Fill a 6 ml albumin comparison tube to the lower graduated mark (4.5m1) with distilled water.
2. Add specimen to the 6 ml mark.
3. Add one (1) 135mg sulfosalicylic acid tablet and invert until dissolved.
4. Let stand for 10 minutes after addition of the tablet, then shake to suspend precipitate.
5. Compare tube to standard tube to determine semi-quantitative value for albumin.

Alternate Procedure:

1. Fill 6 ml albumin comparison tube to the lower graduated mark (4.5m1) with 3% sulfosalicylic acid solution.*
2. Add specimen to the 6 ml mark.
3. Invert the tube several times to mix thoroughly.
4. Let stand 10 minutes, then shake to suspend precipitate.
5. Compare tube to standard tube to determine quantitative albumin.

- To make 3% solution, make 30gm of sulfosalicylic acid up to 1 liter with distilled water. A red or blue color indicates the presence of iron; distilled water is best.

STORAGE

Standards should be stored at ambient temperatures, 4-40C, away from heat and sunlight. Cracking or crazed gelatin is a symptom of freezing.

RESULTS

Compare turbidity of treated urine sample with the turbidity of the standard to match concentration. This procedure will be used to confirm positive proteins on dipstick urinalysis. If confirmatory testing matches the dipstick report out dipstick value. If confirmatory testing is negative report out as negative.